

# How to Prevent Costly Mislabeling and Recalls

*with In-house Digital Label Printing*

It's not uncommon to hear about product recalls in the news. When label content is incorrect, whether the label is incomplete, obsolete, misidentified, or whether front and back labels are mismatched, products can be subject to costly, reputation-damaging recalls, and human health can be put at risk.

For manufacturers in highly regulated industries such as pharmaceuticals, nutraceuticals, medical devices, and food, investigating ways to reduce the possibility of a label mix-up is a critical, constant task. One solution is to collapse the labeling products' time and handling by automating the label printing process with in-house AstroNova digital label printers, making labels just-in-time.



 **AstroNova®**

 QuickLabel®  GetLabels®  TrojanLabel®

# Incorrect Drug Identification

One of the most notorious incidents is from Pfizer, one of the world's largest pharmaceutical companies. In March 2011, Pfizer voluntarily recalled two of their products which were labeled incorrectly by their third-party manufacturer.

1 In that situation, Pfizer's Citalopram, a depression drug marketed as Celexa, was mislabeled as Finasteride, a drug used to treat cancer.

And, in February 2011, Qualitest Pharmaceuticals voluntarily recalled Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500mg 60 count, for being mislabeled as Phenobarbital, USP 32.4 mg 1000 count.

2 Additionally, three lots of Hydrocodone were stored in the same inventory where mislabeled bottles of Phenobarbital were found.



1 DeNoon, D. (March 28, 2011). Recall of Generic Citalopram, Finasteride, Labels of Generic Antidepressant, prostate drug switched. WebMD Health News. Retrieved May 13, 2011, from <http://www.webmd.com/depression/news/20110328/recall-of-generic-citalopram-finasteride>

2 FDA.gov. (February 5, 2011). Qualitest Pharmaceuticals Issues Voluntary, Nationwide Recall of Hydrocodone Bitartrate And Acetaminophen Tablets, USP 10 MG / 500 MG, NDC 0603-3888-20, 60 Count, Lot Numbers T150G10B, T120J10E And T023M10A And Phenobarbital Tablets, USP 32.4 MG, NDC 0603-5166-32, 1000 Count, Lot Numbers T150G10B, T120J10E And T023M10A. Retrieved May 13, 2011, from <http://www.fda.gov/Safety/Recalls/ucm242398.htm>

# ***Incorrect Dosage***



Another case of incorrect dosage comes from Upsher-Smith, which recalled the Jantoven Warfarin anticoagulant drug after pharmacists found that bottles labeled as containing 3mg tablets contained a higher dose of 10mg of Warfarin.





## ***Causes of Mislabeling***

Many mislabeling incidents are caused by a problem that has plagued packaging facilities for the last century: human error. Simply incorrectly selecting the wrong roll of pre-printed labels from inventory can create a severely consequential label mix-up. There are five scenarios under which product labels are mistakenly selected:

## ***Packaging Line Changeover***

On some short-run lines, there are multiple line changeovers per day, and this requires the immediate availability of new labels that match the new work order. In traditional packaging operations, staff must handpick the correct labels from stock to fulfill the order. Digital label printing reduces human error and the likelihood of label mix-ups in this scenario since packaging staff can pre-print batches of labels just-in-time and immediately select them for use.

# ***Product Labels are Obsolete or Changed***

Governmental regulations typically require that the inventory of previously printed labels must be discarded and destroyed to avoid label mix-ups. In traditional packaging operations, this scenario can lead to mislabeling errors as packaging staff become confused as to which labels are new and which are obsolete. Identifying and purging labels in WIP on the production floor or in the stockroom takes time and is subject to the risk of error.

With in-house digital label printing, an obsolete label format can be easily and instantly eliminated from the production database while a new label design can be instantly added. Once a label format is approved, it can be printed immediately if needed.





# ***Front and Back Label Mismatch***

This mix-up occurs when two individual labels are used on a product for front and back facing purposes and one label is selected and placed incorrectly. In-house printers avoid this scenario by printing sequential front and back labels, on the same label liner, so that both labels are matched and available for simultaneous application. Front and back labels can be printed with the same barcode or label control number, if desired, or with serializing information.



# ***Production Floor Decisions***

As production efficiencies demand faster label application and line changeover, packaging line staff may feel under pressure to overlook small label errors, even if printed labels do not match work orders. Label content changes that operators perceive as slight or inconsequential may influence their decisions to use obsolete or misidentified labels. The risk of this scenario can be minimized by printing labels just-in-time so that correctly printed labels are at hand.



# **Misapplied Clinical Trial Labels**

In situations such as clinical trial labeling, it is critical that products are matched to labels that are accurately printed with unique information such as batch numbers, strength/potency, directions for use, color code, expiration date, and storage requirements. Unfortunately, drug labels can appear similar to the human eye, making label mix-ups more likely.

By printing labels and pulling variable information content directly from a database in one seamless operation, AstroNova printers produce labels without the need for human intervention and each label is then available to be sequentially applied to each product.



 QuickLabel®



***How In-House  
Digital Label  
Printers Help  
Avoid Labeling  
Errors that  
Lead to Recalls***



## ***Maintaining In-House Control with Just-in-Time Printing***

Maintaining constant supervision over labels throughout the workflow is a critical step to avoiding labeling errors. Oversight is lost when labels are sent to a stock location and stored until a later date.

The possibility of a label mix-up is vastly reduced when labels are digitally printed on-site and utilized moments after printing, as packaging line staff never lose eye contact and custody of the labels.

As in-house printing solutions, QuickLabel and TrojanLabel produce batches of labels instantaneously.

When work orders are received, blank labels are with the correct content, including graphics, text, barcodes, and variable information. As soon as labels are printed, operators can immediately load them onto the label applicator system and apply them to the correct batch of products, eliminating any need for label inventory, reducing the need for a costly vision system on a packaging line, and maintaining constant supervision over both the labels and products, dramatically reducing the chances of a label mix-up.

# Database-Driven Label Printing

Label content printed by AstroNova printers are easily controlled by software that links directly to a database, ensuring the latest, approved information is printed for each SKU on any given packaging line. There's no searching for a label with the right content, and therefore no risk of selecting the wrong label from a shelf in the stockroom. The printer seamlessly presents the correct label with barcodes, descriptions, color images, and other validation content.





# Confirmation of Correct Label Selection via Touchscreen

The AstroNova printing process is as simple as an operator walking over to the touchscreen display on the system, choosing the correct label by selecting a job name or other identifier, and then confirming the selection before printing by merely reviewing the thumbnail picture of the label on the touchscreen. Alternatively, batches of labels can be automatically printed by digitally sending a batch to be printed over a network.

To ensure the correct label adheres to the right product package, operators can print labels in a mobile workstation located next to the products requiring labeling, further reducing the possibility of human error during the labeling process.

Whenever important label information needs to be changed, AstroNova printers are ready to print updated labels on-demand. With no printing plates required, there are no new expenses, no delays, and no limitations in immediately implementing approved changes to product labels.

# AstroNova Understands Your Application

Today, thousands of manufacturers, processors, and retailers worldwide are increasing their sales revenue and profit margins by labeling in-house. With over 50 years of innovation and expertise, let AstroNova help your business stay ahead of potential manufacturing nightmares by taking control of your labeling today!

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